RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1, 5-8, 10-14, 17-22, 26-33, 35-41, 43-45, 49-52, and 54 were pending. Claims 28-30 are cancelled. No new matter has been added. Thus, claims 1, 5-8, 10-14, 17-22, 26-27, 31-33, 35-41, 43-45, 49-52, and 54 are presented herein for reconsideration.

B. Claims rejection under 35 U.S.C. § 102(a)

Claim 8 is rejected under 35 U.S.C. § 102(a) as being anticipated by Kumar *et al.* (*Plant Cell Rep.* 18:59-63, 1998; published November 1998). In response Applicants respectfully direct the Examiner's attention to Appendix 1, an Inventors' Declaration under 37 C.F.R. § 1.131, with accompanying **Exhibit A**. The Declaration demonstrates that the method of claim 8, comprising use of activated charcoal to induce embryogenesis from cotton callus tissue, was conceived of and reduced to practice prior to the November 1998 publication date of Kumar *et al.* Thus, the reference is no longer prior art and withdrawal of the rejection is respectfully requested.

C. Claims rejections under 35 U.S.C. § 102(b)

(1) Rejection of Claim 1 over Smith *et al.*

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Smith *et al.* (*In Vitro* 13:329-334, 1977), in that Smith *et al.* are alleged to disclose a method of culturing cotton callus under dark conditions. Applicants respectfully traverse as follows:

As indicated in the previous response, the Smith *et al.* reference describes culture, and more specifically, callus initiation, of non-regenerable plant cells from *Gossypium arboreum*, a diploid wild relative, and not of regenerable cells of the cultivated cotton crop species *Gossypium hirsutum* (a tetraploid) exemplified by variety Coker 312 as described in the Specification, for instance, at

page 24, line 13. It was well known in the art as of the filing date that regeneration of diploid *Gossypium* sp. was not enabled. For example, Applicants draw the Examiner's attention to Sakhonokho *et al.*, (*In Vitro Plant* 40:177-181, 2003), and to a description of the Sakhonokho publication by its authors at the following USDA-ARS website: https://www.ars.usda.gov/research/publications/publications.htm?seq_no_115=138688 (copy attached as **Appendix 2**).

In particular, **Appendix 2** explicitly notes in the Interpretive Summary that, at least as of July 28, 2003, which is well after the December 18, 1998 priority date of the present application, "To [the authors'] knowledge, there is no report on somatic embryo and plant regeneration from the diploid cultivated species of cotton" (*i.e. G. arboreum*). This statement clearly indicates that the state of the art as of the filing date of the present application, and for that matter when the cited Smith reference was published, was that *G. arboreum* had not successfully been regenerated from tissue cultured cells such as callus cells. The Smith reference simply does not describe regenerable cotton cells, or enable one of skill in the art to obtain regenerable cotton cells, whether of *G. arboreum* or from any other species.

Additionally, one of skill in the art would understand that methods for induction of cotton callus or for cotton embryogenesis are distinct, as evidenced by the fact that methods for cotton callus induction were reported in the art for many years (*e.g.* the cited 1974 Davis publication) before successful embryogenesis, embryo maturation, and regeneration of cotton cells was achieved. One skilled in the art would not use treatments described only to form callus and also expect induction of embryo formation and maturation, resulting in regeneration of plants.

The Action nonetheless asserts that the preamble of the claim, reciting the term "regenerable" is not to be given any patentable weight, and that this term is only found in the

preamble. However, Applicants submit that the body of the claim (*i.e.* the term "said cotton tissue") refers back to the preamble and depends on it for completeness. Thus the recitation of, for instance, "regenerable non-embryogenic cotton callus tissue or embryogenic cotton tissue" must properly be considered in understanding the meaning of the term "said cotton tissue" in the claim body. Since the cited reference does not recite all of the properly understood limitations of claim 1, it does not anticipate the claim. Applicants thus respectfully request that it be withdrawn.

The Action also asserts (Action, bottom of page 4) that some cell growth was described by Smith even under dark conditions. However, Applicants' representative, having read the reference, does not find any data demonstrating cell growth in dark conditions. Clarification is thus respectfully requested, since as was noted in the previous response, data from cell growth in dark conditions is not even shown.

(2) Rejection of Claim 1 over Hirimburegama *et al.*

The Action also rejects claim 1 under 35 U.S.C. §102(b) as being anticipated by Hirimburegama *et al.* (*J. Nat. Sci. Council Sri Lanka* 22:305-315, 1994). The Hirimburegama reference is stated to disclose a method for culturing cotton tissue in complete darkness. Applicants respectfully traverse as follows:

The Hirimburegama reference does not describe regenerable cell cultures of cotton (*G. hirsutum*). The Action asserts that the preamble of the claim, reciting the term "regenerable" is not to be given any patentable weight and that this term is only found in the preamble of claim 1. However, as noted above, Applicants submit that the body of the claim (*i.e.* the term "said cotton tissue") refers back to the preamble and depends on it for completeness. Thus the recitation of, for instance, "regenerable non-embryogenic cotton callus tissue or embryogenic cotton tissue" must properly be considered in understanding the meaning of the term "said cotton tissue" in the claim

body. As the cited reference does not recite all of the properly understood limitations of claim 1, it does not anticipate the claim. Applicants thus respectfully request that the rejection be withdrawn.

(3) Rejection of Claims 8, 10, 11 over Davis *et al.*

Claims 8, 10, and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Davis *et al.* (*In Vitro* 9:395-398, 1974). Davis is alleged to disclose a method of culturing regenerable cotton leaf explant tissue in media containing ascorbic acid. Applicants respectfully traverse.

As an initial matter, Applicants note that this 1974 reference is dated well before any accepted report concerning production of regenerable cotton cells, or of regenerated plants from cultured cotton cells. Applicants do not find any mention of regenerable cotton cells in this reference, and for cotton only a description of callus and cell suspensions induction, with no mention of cell regenerability or of cotton plant regeneration. Although the term "regeneration" is used at page 397, left column, 3rd line, it is used in the context of vigorous callus growth, and clearly does not refer to regeneration of differentiated plants from non-differentiated cells, as the term would be understood by those of skill in the art and in view of the teachings of the Specification, for instance at page 10, line 17. Additionally, the Davis reference is not concerned with promoting embryogenesis (*e.g.* claim 8), which is not described, but is instead concerned with maintenance of undifferentiated callus cultures (*e.g.* see introductory paragraph). Since the cited reference does not relate to or recite all of the properly understood limitations of claim 1, it does not anticipate the claim. In view of this, removal of the rejection is respectfully requested.

(4) Rejection of Claims 28-30 over Firoozabady *et al.*

Claims 28-30 are rejected under 35 U.S.C. § 102(b) as being anticipated by Firoozabady *et al.*, in that Firoozaboady is asserted to disclose a method of cotton transformation comprising placing cotyledon tissue on filter paper to induce callus formation. Applicants have cancelled

claims 28-30 and submit that the rejection is now moot. Removal of the rejection is respectfully requested.

(5) Rejection of Claims 36-37 over Rangan

Claims 36-37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rangan *et al.* (U.S. 5,244,802), in that Rangan is asserted to disclose a method of regeneration of transgenic cotton tissue in media containing amino acid hydrolysate. Applicants respectfully traverse.

Although the Action alleges that the Rangan reference discloses culturing of transgenic cotton tissues in a media containing amino acid hydrolysate, the reference citations provided in the Action do not describe this. Thus, the callus referred to at column 13, lines 5-7 and 66-68 is not transgenic callus. The Action also cites column 10, line 36, and Examples 9-14 of Rangan ('244) in this regard. Applicants respectfully submit that the cited reference does not recite all of the limitations of the claims. In particular, column 10, line 36, apparently refers to tissues that are not yet transformed. Thus, this does not lead one of skill in the art to utilize amino acid hydrolysate in culturing transgenic tissue, since one of skill in the art would be well aware that growth conditions following a transformation attempt would likely differ from those before transformation. Use of the hydrolysate would be just one among numerous variables that might be considered by a practitioner. Further, the teachings of Example 8, wherein use of the hydrolysate is described, clearly refer to culture of non-transgenic tissue. Similarly, the '244 specification, at Examples 9-14, does not describe culture of transgenic tissue with amino acid hydrolysate. Instead, Example 9 describes use of a liquid culture for growth of cotton cells that are undergoing the first steps of a transformation process. This media is not the solidified media of Example 8, column 13, that contains amino acid hydrolysate, but is instead the liquid media of Examples 6 or 7, that does not contain the hydrolysate. Examples 10-13 are stated (*e.g.* column 14, line 7) to use the media described in

Example 1 and 9, which again does not contain the hydrolysate. Example 14 utilized the conditions of Examples 7 or 10 (*e.g.* column 17, line 5; column 23, line 45), and so did not use media with amino acid hydrolysate to grow transgenic cells. Thus the allegation that transgenic cotton tissue was cultured on media containing an amino acid hydrolysate supplement is mistaken. Removal of the rejection is respectfully requested.

D. Claims Rejection under 35 U.S.C. § 103(a)

(1) Rejection of Claims 1, 5-6, 8, 10-12, 14, 17, and 18 over Smith *et al.*, in view of Davis *et al.* and Further in view of Chi *et al.*

The Action rejects claims 1, 5-6, 8, 10-12, 14, 17, and 18 under 35 U.S.C. § 103(a) as being unpatentable over Smith *et al.*, in view of Davis *et al.* and further in view of Chi *et al.* Applicants respectfully traverse.

Applicants again note that the Smith reference is not concerned with cell culture of regenerable cotton tissue, and further provides no data concerning growth of cotton tissue under dark conditions. The Davis reference likewise does not relate to culture of regenerable cotton cells, which were not even known in the art at the time of publication, or to use of an antioxidant such as ascorbic acid "to promote embryogenesis" [*e.g.* claim 8]. To the extent that Davis understands that addition of ascorbic acid may work, it is stated to reduce pigment formation (abstract; also p.396 right column). Additionally, the reference specifically relates to establishment of callus and cell suspension cultures of cotton , and attempts to identify conditions under which embryogenesis does not occur – *i.e.* maintaining callus culture separate from embryos (Davis, page 395, left column, introductory paragraph). One of skill in the art would therefore not apply the teachings of Davis in order to practice the currently claimed invention, which broadly relates instead to methods for

promoting embryogenesis and regeneration of cotton cells, rather than maintenance of undifferentiated growth.

Chi *et al.* is conceded by the Action to relate to *Brassica* cell culture rather than cotton culture. The Action alleges that one of skill in the art would have nevertheless routinely applied the teachings of Chi, derived from *Brassica* research, to cotton cell culture, apparently because both are dicot plants. Applicants respectfully submit that one of skill in the art of cotton cell culture would not have routinely done this, since *Brassica* (Brassicaceae) and cotton (Malvaceae) are not closely related. Even among Malvaceae such as okra and cotton, cell culture conditions may vary considerably. The cited Davis reference, for instance, indicates that even cotton and okra cell culture media were not routinely interchangeable (*e.g.* Davis, paragraph bridging the column on page 397; and discussion, first paragraph, p. 397), in spite of these two species being closely related members of the Malvaceae. One of skill in the art would simply not have applied the teachings of a reference from *Brassica* research without the additional experimentation required to establish its relevance to cotton culture. The cited references therefore neither teach nor suggest all elements of the claims to one of skill in the art, and further no motivation to combine them is present. Thus a *prima facie* case of obviousness has not been established, and Applicants respectfully request withdrawal of the rejection.

(2) Rejection of Claims 7, 13, 19-22, 26-27, 31-33, and 35 over Smith *et al.*, in view of Davis *et al.*, Chi *et al.*, and further in view of Firoozabady *et al.*

The Action also rejects claims 7, 13, 19-22, 26-27, 31-33, and 35, under 35 U.S.C. § 103(a) as being unpatentable over Smith *et al.*, in view of Davis *et al.*, Chi *et al.*, and further in view of Firoozabady *et al.* Applicants respectfully traverse.

As noted above, the teachings of Smith, Davis, and Chi do not teach one of skill in the art how to grow regenerable cotton cell cultures under conditions that promote embryogenesis and regeneration, for instance by use of dark growth, antioxidant, and AVG. Further, as noted above, one of skill in the art would have no motivation to combine various of the teachings found therein. The addition of Firoozabady, apparently cited as it relates to culture of transformed cotton cells on solid support such as filter paper, does not cure this defect.

The Action's choice of these parameters among the many that exist in the references' plant cell culture experiments is clearly done with the benefit of hindsight. A person of ordinary skill in the art would have had no motivation to combine the various cited portions of these references, to the extent that they even relate to culture of regenerable cotton cells, or any suggestion of success in practicing the curently claimed subject matter. A *prima facie* case of obviousness has therefore not been established, and removal of the rejection is respectfully requested.

(3) Rejection of Claims 36-38 over Smith *et al.*, in view of Davis *et al.* and Chi *et al.* as applied to claims 1, 5-6, 8, 10-12, 14, 17, and 18, and further in view of Rangan *et al.*

The Action rejects claims 36-38 under 35 U.S.C. § 103(a) under 35 U.S.C. § 103(a) as being unpatentable over Smith *et al.*, in view of Davis *et al.* and Chi *et al.* as applied to claims 1, 5-6, 8, 10-12, 14, 17, and 18, and further in view of Rangan *et al.* Applicants respectfully traverse.

As noted above, Smith, Davis, and Chi do not relate to culturing of transgenic embryogenic cotton tissue on media containing an amino acid hydrolysate. The addition of Rangan does not cure this defect, since the use of media containing the hydrolysate is only described by Rangan as occurring in the context of culture of not yet transformed tissue. Furthermore, the Action's choice of these particular parameters among the many that exist in the multiple cited references' plant cell culture attempts is clearly done with the benefit of hindsight. A person of ordinary skill in the art

would have had no clear motivation to combine these various portions of these references among many other possible combinations of culture conditions. A *prima facie* case of obviousness has therefore not been established, and removal of the rejection is respectfully requested.

(4) Rejection of Claims 45 and 49 over Smith *et al.*, in view of Gould *et al.*

The Action rejects claims 45 and 49 under 35 U.S.C. § 103(a) under 35 U.S.C. § 103(a) as being unpatentable over Smith *et al.*, in view of Gould *et al.* (*Plant Cell Rep.* 10:12-16, 1991). Applicants respectfully traverse. As noted above, Smith *et al.* do not describe growth of regenerable cotton tissues. They also provide no actual data regarding the growth of cotton tissues in the dark, as the reference includes only cursory statement that cotton tissues grew better under low light conditions than under dark conditions (page 333, left column). Further, even if such a statement were relied upon by a practitioner, it would teach against the utility of dark growing conditions for growth of cotton tissues, and against further experimentation utilizing dark growing conditions in order to improve cotton cell culture. The addition of Gould does not cure this defect. Since the cited art does not include all elements of the claims, the claims can not be deemed obvious. Removal of the rejection is thus respectfully requested.

(5) Rejection of claims 50-52 and 54 over Smith *et al.*, in view of Davis, Chi, Rangan, and Firoozabady as applied to claims 39-41, 43, and 44, and further in view of Gould.

The Action rejects claims 50-52 and 54 under 35 U.S.C. § 103(a) under 35 U.S.C. § 103(a) as being unpatentable over Smith *et al.*, in view of Davis, Chi, Rangan, and Firoozabady as applied to claims 39-41, 43, and 44, and further in view of Gould. Applicants respectfully traverse. Again, as noted above, Smith *et al.* do not describe growth of regenerable cotton tissues. They also provide no actual data regarding the growth of cotton tissues in the dark, as the reference includes only

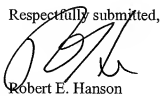
cursory statement that cotton tissues grew better under low light conditions than under dark conditions (page 333, left column). Further, even if such a statement were relied upon by a practitioner, it would teach against the utility of dark growing conditions for growth of cotton tissues, and against further experimentation utilizing dark growing conditions in order to improve cotton cell culture. As noted above, Davis does not relate to culture of regenerable cotton cells. Chi does not relate to cotton cell culture, and its teachings, related to *Brassica,* would not be understood to routinely apply to cotton. The addition of Gould does not cure these defects. Since the cited art does not include all elements of the claims, the claims can not be deemed obvious. Removal of the rejection is thus respectfully requested.

E. Conclusion

In view of the above, it is submitted that all of the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned at (512) 536-3085 with any questions, comments, or suggestions relating to the references patent application.

Respectfully submitted,



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